9. (new) The process of claim 8, wherein the probability of each diagnosis is determined prior to conducting a patient examination for a particular disease and redetermined following the outcome of the patient examination, thereby incorporating relevant information in the form of a linked succession of likelihood ratios from the examination into the post-examination calculation.

10. (new) The process of claim 8, including multiplying a chain of likelihood ratios to produce a product that refines the accuracy of ranked probabilities.

11. The process of claim 1, including continuously updating and expanding the statistically accrued evidence-based data by using the common system template to add statistical information from patient populations from a plurality of input sources.

REMARKS

Applicant wishes to thank the examiner for her responsiveness and thoroughness in preparing the office action. The examiner's overall substantive analysis of the claims is well-taken by the applicant.

The examiner will appreciate that this case originates from a provisional patent application filed in 1999 that was converted into a utility application in 2000. The provisional filing reflected the inventor's best known embodiment at that point in time. During the four years the utility application was pending, the invention passed through a series of developmental stages that will hopefully lead to a viable commercial service in the near future. If it would be useful in helping the examiner understand the merits of the invention vis-à-vis the prior art, the invention is presently in beta testing and applicant can provide the examiner with a web-based demonstration, in her office, if she so desires.

The web-based implementation of the invention makes it a powerful diagnostic tool in the medical field. The claimed web-based template system for accruing evidence-based data, as set forth in claim 1, provides a vehicle for providing an adaptive, real-time system that automatically updates for all users at the same time. The claimed matrix of input variables and related outcomes that are evidence-based diagnoses taken from prior patient populations provides a different kind of mathematical analytical tool from prior art systems. One of its chief advantages is that is has virtually unlimited scalability – which means that input variables, and their relative contribution to the probability of each outcome, can be added or deleted easily – something that is difficult to do with the prior art systems that employ common statistical regression analysis.

During the last five years, the applicant's developmental activity has been ongoing (on a confidential basis) and the applicant's market focus has shifted. While the invention can be used by potential *patients* as a self-diagnostic tool, it is presently believed that the invention is better utilized by *doctors* as a diagnostic tool in hospitals, clinics, and the like, for incoming patients.

This paper is supported by the declaration of the inventor, Dr. Victor Levy, who summarizes the economic problems and needs in healthcare. There has been a long-felt need in the medical field for a reliable predictive tool that provides more efficient diagnoses of diseases – for the reasons stated in Dr. Levy's declaration. Attached to Dr. Levy's declaration are a series of more recent publications that support Dr. Levy's statements and confirm that the type of system claimed here is needed in the medical field. It is the claimed web-based system template (or networked system in lieu of a web-based system that is otherwise equivalent to the web, *i.e.*, LAN, WAN, or other data-sharing networks, which applicant considers to be legally equivalent

to "web-based" for the purpose of claim interpretation) that enables a viable implementation of the type of system these articles state are needed in the field.

The examiner should appreciate that, to a certain degree, the description in the application suggests use as a self-diagnostic tool, because the applicant was focused on that market implementation in 1999, more so than others. Nevertheless, the description also suggests that the invention can be used as a tool by doctors. The underlying methods and processes that make up the invention claims are the same, either way. Moreover, applicant does not intend to restrict invention claims for one subcategory of use in the medical field (*i.e.*, self-diagnosis) as opposed to another (*i.e.*, doctor-diagnosis), as is now reflected in amended claim 1. The examiner will appreciate that amended claim 1 continues to be generally restricted to the diagnosis of medical symptoms – which is the same, in a general way, as original claim 1.

It is believed by applicant that the examiner's search relating to "Invention I" (which the examiner accurately identified as "health care management") resulted in an identification of what applicant believes to be what is probably the most relevant prior art reference (*i.e.*, Iliff) from the patent literature, although applicant wishes to call the examiner's attention to other patents and publications identified below and on a supplement information disclosure statement submitted herewith. As applicant understands it, "Invention I" relates to health care and not other kinds of expert systems.

Given that many years have passed from the non-provisional application filing date, applicant's attorney has prompted applicant to once again revisit applicant's obligations under 37 C.F.R. § 1.56. As a result, applicant is submitting a supplemental information disclosure statement ("IDS") that identifies newly discovered prior art that may be material to patentability. The supplemental IDS should be read in connection with the remarks that follow, and applicant

wishes to call the examiner's attention to the Pozen et al. publication, in particular, and the Selker patents. If the examiner has any questions concerning the IDS, applicant respectfully requests that the examiner contact applicant's attorney so that any questions may be resolved while the present application remains pending.

On a general level, applicant's claims are distinguishable from much of the prior art because applicant is claiming a purely "evidence-based" system (*see, e.g.*, claim 1, lines 3-5) in contrast to a "rules-based" system. While the distinction may seem subtle, it is nevertheless an important one.

Rules-based systems are well-known and familiar to those skilled in the art. For example, consumers who request online self-help support services on the Internet are typically transferred into a rules-based system that attempts to solve the consumer's problem. This type of system has a logical structure that follows a "yes" or "no" decision tree matrix until the problem is either solved or not solved. "No" answers (*i.e.*, problem "not solved") direct the requester through a different decision tree for another potential solution, until a solution is reached, or all of the possibilities are exhausted.

An evidence-based system, in accordance with the present invention as claimed, provides the user with multiple potential solutions, at the same time, and ranks them according to probability. In this respect, it is believed that the present invention is the first of its kind. When applied to the medical field, as per the information set forth in the specification, a patient may provide a series of symptoms into a web-based database (this could be done on a self-help basis or it could done by the patient's doctor). Based on the symptoms that are input, the system outputs a plurality of potential disease categories (or potential diagnoses) and ranks them

according to probability of occurrence – which is based, simply, on statistically accrued evidence.

For example, when a person walks into a hospital complaining of chest pain, then based on the total population of others who previously complained of chest pain, it is statistically possible to predict that there is a certain probability that the complaining person is having a heart attack as opposed to another diagnosis (because accrued statistics will indicate that "X" number out of 100 people who enter a hospital complaining of chest pain are suffering from a heart attack).

Depending on the symptoms expressed by the patient (as input variables), the evidence-based system will output a first probability that the person has diagnosis "A," a second probability that the patient has diagnosis "B," a third probability that the patient has diagnosis "C," and so on. The probability factors allow diseases and diagnoses to be identified according to the highest probability. An advantage to this type of system is that the "highest" probability may later be found to be incorrect after taking an additional history, conducting additional physical examinations, or including other applicable tests for the underlying disease. In such case, the invention updates automatically. The advantage that the invention provides is that all users are updated across the network. For example, if hospital "A" inputs new data that alters the probabilities of various diseases and diagnoses, that data alters the probabilities of the diseases and diagnoses at hospital "B," at virtually the same time.

The evidence-based system, according to the invention, utilizes likelihood ratios ("LR"). Each LR is a type of "weighed" statistically determined association between an answer to a question and each potential diagnosis, which evolves, and is refined, as an ever-increasing number of diagnosed patient examinations are accrued by the system. The LRs are automatically

selected from an undiagnosed patient's signs, symptoms, and laboratory tests (which are input into the common system template as input variables). The product of LRs can refine the ranking of that disease's list of potential diagnoses instantaneously. As indicated above, the system can immediately recalculate a new series of probabilities. A new priority ranking of diagnoses can thereby be created in a continuously updating fashion. Displaying and recalculating all of the probabilities at the same time is inherently faster than a rules-based system, and more akin to the problem solving ability of the human mind.

As will be further discussed below, the applicant concedes that rules-based diagnostic systems have been both developed in the medical field and are based on statistical evidence to a certain degree. Iliff is a class example of a rules-based system. Pozen relies on evidence-based data, but then implements solutions via a rules-based calculation method (a sequence of seven variable steps input linearly as "1" or "2" on a calculator). The fundamental problem with a rules-based system is that it is not as adaptive, nor as accurate, as a purely evidence-based system.

A rules-based system is inherently less accurate, or has the potential to be less accurate over time, because it cannot be updated on an ongoing or real-time basis. In this respect, a rules-based system can be likened to a flow chart prepared by a software programmer before code is written. The flow chart implements logical "yes" or "no" or "present" or "absent" decisions based on a medical diagnostic method known at the time. If the diagnostic method changes, then the flow chart may become out of date, or the entire system may shift toward producing erroneous results, which would require new logical programming as a corrective measure. For example, Pozen describes what is essentially an ongoing survey of incoming patients. Data is

input on a form and then used to predict a disease. If the paper input form is changed, then it creates a ripple of downstream changes that eventually requires reprogramming the calculator.

A related problem with a rules-based system is that it tends to output solutions in black and white, as though there is a simple "yes or no" textbook answer to a particular set of variables (or symptoms, in the case of medical treatments) that are input into the system. Anyone who has been captured by a voice mail answering system, with no chance of exit once the answering possibilities have been exhausted, will understand that logical programming, based on any rules, is not infallible.

Rules-based systems have the potential for becoming dangerous when used in the medical field because a doctor's assemblage of actual patient evaluations and outcomes (experience) simply is not amenable to incorporation in a typical computer program. Quite simply, some doctors will use a process of elimination to determine a patient's disease. It is true that this type of diagnostic methodology can be transferred into a rules-based system. On the other hand, more experienced doctors immediately recognize or suspect subtle qualitative differences between diseases based on their own past experiences – which is why doctors with more experience tend to be better than doctors with less experience. A shortcoming of a rules-based system is that one simply cannot program experience of this kind very well in a flow chart.

Related to the above, the applicant asks the examiner to bear in mind that a rules-based system requires people with medical expertise, on the one hand, and computer programming expertise, on the other. This creates a balance between those who understand medical problems and those who understand programming but lack the same medical experience or understanding of the underlying medical problems. As a consequence, it is believed that effective

implementation of a rules-based system in the medical field may, in fact, have a relationship to the medical knowledge of the programmer, which may be lacking.

An evidence-based system shifts the balance the other way (*i.e.*, away from the expertise of the programmer) because it outputs a range of diagnoses that is simply based on statistically-accrued data (*i.e.*, data based on actual experiences of treating physicians). Returning to the chest pain example, after 200, 500, or 1,000 patients are analyzed using an evidence-based system, the accuracy of the predicted probability of a heart attack, as well as simultaneously competing diagnoses, becomes refined on an ongoing basis, and continues, up until a theoretically infinite number of patients have been examined. The power of this kind of tool is enhanced when many hospitals or treatment centers, using the same data input templates (see Figures 11, 12, 13 in specification), are networked into a single database because it creates ever-expanding amounts of data. Data input can be accomplished virtually instantaneously across the network every time a doctor examines a patient. Moreover, with a web-based system, it can be done by a doctor in an emergency room, at bed-side in a hospital room, in an ambulance, or elsewhere.

Contrasting this type of system, again, to a rules-based system, the quality of disease management improves in real-time on an ongoing basis without rewriting software logic. Updating a rules-based system is much like software updates that are provided on a periodic basis.

Turning now to the specific rejections made by the examiner, applicant respectfully submits that the claims pending in the application are allowable.

1. **Examiner's Claim Rejections – 35 U.S.C. § 112**.

The examiner rejected claim 5 under 35 U.S.C. § 112 for indefiniteness. Claim 5 has been canceled, making the examiner's rejection moot.

2. **Examiner's Claim Rejections – 35 U.S.C. § 101**.

The examiner rejected original application claims 1-4 under 35 U.S.C. § 101, alleging that the claimed invention is directed to non-statutory subject matter. It appears that the examiner focused on the lack of any claim language that removes the claim from something that is purely an algorithm and can be performed in the mind of the user or by use of a pencil and paper (*see* Office Action, p. 5, second paragraph). Applicant respectfully submits that this rejection is overcome by the addition of the language "providing an automated database as a real-time web-based system that includes statistically accrued, evidence-based data . . ." (*see* amended claim 1, lines 3-5).

3. **Examiner's Claim Rejections – 35 U.S.C. § 103**.

The examiner rejected original application claims 1-2 and 4 under 35 U.S.C. § 103 as being unpatentable over Haessler et al., U.S. Patent No. 4,130,881 ("Haessler") in view of Iliff et al., U.S. Patent No. 6,206,829 ("Iliff").

First, it is respectfully submitted that Iliff is more pertinent to the patentability of the present invention than Haessler because Iliff teaches an automated "intelligent" health care system that provides doctors with a diagnostic tool. This is closely similar to the present invention. Nevertheless, regardless of which reference (or combination thereof) is deemed to be the most relevant, amended claim 1 now calls for a process for facilitating diagnosis of medical systems that involves "statistically accrued, evidence-based data that is input from multiple sources via a common web-based system template" (*see* claim 1, lines 4-6). Given the foregoing

definition of "evidence-based" as opposed to "rules-based" in the above discussion, it is respectfully submitted that amended claim 1 is distinguishable over Iliff (and any other prior art reference of record), because Iliff is a rules-based system. In this respect, the examiner's attention is directed to Figs. 10A and 10B in Iliff, which represents, precisely, the type of flow-chart based system that Iliff represents, as discussed above. None of the prior art references disclose evidence-based systems for diagnosing diseases.

Second, and related to the above, claim 1 calls for "common template includes a matrix of a plurality of independent input variables coupled with a plurality of outcomes for each input variable . . ." (*see* claim 1, lines 7-10). Neither Iliff, Pozen, Selker, nor any of the prior art of record discloses the use of statistically accrued evidence-based common templates, arranged in the way claimed, to report the "probabilities for each diagnosis" (*see* claim 1, lines 18-19). For this additional reason, it is respectfully submitted that claim 1, as amended, is allowable over the prior art of record.

As to new claim 8, none of the prior art references teach "providing a ranked probability . . . by using an algorithm that generates at least one likelihood ratio for each independent variable." The examiner will appreciate that the implementation of likelihood ratios is clearly described in the specification and is unique to the claimed web-based system template. This further limitation sets the claimed evidence-based invention apart from the prior art.

New claim 9 calls for determining a likelihood ratio for a patient prior to conducting the patient's examination and re-determining it following the examination. Once again, this is a feature that is not disclosed in the prior art references.

New claim 10 calls for multiplying a chain of likelihood ratios to produce a product that refines accuracy.

Finally, new claim 11 calls for continuously updating and expanding the statistically accrued evidence-based data on a real time basis by using the common system template to add statistical information to the database that is acquired over time. Systems like Iliff or Pozen are incapable of implementing real time changes.

The examiner's rejection of original application claims 2-4 is rendered moot given the cancellation of these claims.

4. Examiner's Claim Rejections – 35 U.S.C. § 102.

The examiner rejected application claim 5 under 35 U.S.C. § 102(b) as being anticipated by Iliff. That rejection is now moot, given the cancellation of claim 5. However, applicant wishes to point out that a rejection under 35 U.S.C. § 102(b) is technically incorrect. Applicant presumes that the examiner intended to apply 35 U.S.C. § 102(a) to the claim.

5. Other Issues.

For reasons discussed above, applicant respectfully submits that, given the claim amendments submitted here, the examiner's provisional restriction requirement is no longer applicable in the same way. The claim amendments essentially restrict the claims to Invention I, given applicant's understanding that the examiner views Invention I as relating to "health care management." Claim 6 is now canceled which makes a restriction between Inventions I and II a moot point. Likewise, claim 7 has been canceled which makes the examiner's restriction vis-à-vis Inventions I and III a moot point.

As applicant understands it, the examiner views Invention III as including a broader range of "expert" systems that would include systems well outside the health care field (*e.g.*, automated manufacturing systems, etc.). It is not applicant's intent to claim inventions that involve processes for designing algorithms (Invention II) or "expert" systems (Invention III) in

other fields, at least in the present application. Nevertheless, applicant is not waiving his right to later claim (in a divisional, continuation, etc.) any invention, regardless of class, so long as it is supported by the description set forth in the application.

Finally, applicant requests that the examiner review and consider the supplemental information disclosure statement and Dr. Levy's declaration, submitted with this paper. Set forth below is a chart, for the examiner's convenience, that will assist the examiner in comparing the present invention with what applicant believes to be the most relevant references.

	Iliff	Pozen	Hendrickson	Haessler	*Levy*
Rules-based	Yes	Yes	Yes	Yes	No
Purely evidence-based	No	No	No	No	Yes
Template for construction of predictive tool	No	No	No	No	Yes
Actual probability mediated	"self described" only	Yes	"self described" only	No	Yes
Computed probabilities from submitted evidence-based data automatically	No	No	No	No	Yes
Expert panel constructs "rules"	Yes	Yes	Yes	Yes	No
Academically rigorous	No	Yes	No	NA (only history)	Yes (evidence-based)
Web-enabled	Yes	No	Yes	No	Yes
Continuous automatic updating of data	No	No	No	No	Yes
Multiple applications (diagnosis & quality assurance)	No	No	No	No	Yes
Routine manual updates	Yes	No	No	Yes	No
User/client customizable	No	No	Yes	No	Yes
Aggregates "collated" raw, prospective data, which undergoes calculations built into system for functionalization of the tool	No	No	No	No	Yes

For all of the foregoing reasons, it is respectfully submitted that the claims that are now pending in this case are in condition for allowance. Applicant wishes to request a telephone interview with the examiner to discuss the prior art and any other questions the examiner may

have. Applicant will contact the examiner to request an interview time that is mutually convenient.

Respectfully submitted,

VICTOR LEVY

By: _____

Bruce A. Kaser
Registration No. 31,531
DAVIS WRIGHT TREMAINE LLP
2600 Century Square
1501 Fourth Avenue
Seattle, WA 98101-1688
Telephone: (206) 628-7653

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